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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,873	03/11/2004	Vincent P. Stanton JR.	11926-068002	6587
26161	7590	12/27/2005	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			WILDER, CYNTHIA B	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/798,873

Applicant(s)

STANTON, VINCENT P.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's preliminary amendment filed on March 11, 2004 is acknowledged and has been entered. Claim 1-16 has been cancelled. Claims 17-24 have been added. Claims 17-24 are pending in the instant invention.

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at pages 53, 93-95, 100, 102, 104, 105 and 137. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 101 (lack of Utility)

3. The pending claims 17-24 have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" requirement, Federal Register, vol. 66, no. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility:

"Credible Utility" - Where an Applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided. An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the Applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or

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forensic or diagnostic markers. Therefore, the credibility of such assertion would not be question, although such use might fail the *specific* and *substantial* tests (see below).

"Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrast with a *general* utility that would be applicable to the broad class of the invention.

"Substantial Utility" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Well established Utility" - A specific, substantial and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone, or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA.

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 17-24 are rejected under 35 U.S.C. 101 because the claimed inventions lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed isolated nucleic acid probe comprising at least 15 nucleotides which hybridizes under stringent conditions to a variant human cytochrome -450 (CYP3A4) gene having a T to C variance at nucleotide 732 and does not hybridize under stringent conditions to a human cytochrome P-450 (CYP3A4) gene not having a T to C variance at nucleotide 732 is not supported by a specific and asserted utility because the disclosed use of the isolated nucleic acid molecule is not specific and is generally applicable to any nucleic acid molecule. For example, the specification at pages 26-28 disclose the isolated nucleic acid molecule as useful as a probe for hybridization reactions or primers in an amplification reaction specifically identify variant

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forms of a gene, such as the genes recited in Table 3. These are non-specific uses that are applicable to nucleic acids in general and are not particular or specific to the nucleic acids claimed.

The claimed invention is not supported by a substantial utility because no substantial utility has been established for the claimed isolated nucleic acid molecule or the gene product. For example, the specification teaches that the isolated nucleic is used as a probe to specifically identify variants forms of a gene, such as a T to C substitution at position 732 of the cytochrome P-450 (CYP3A4) gene. The specification states that the variant form(s) of a gene as listed in the cited Table 3, e.g., the T to C substitution at position 732 of the CYP3A4 gene, is associated with a response to a drug. The specification continues by stating that the frequency of a specific variance or variant form of the gene may correspond to the frequency of an efficacious response to administration of a drug. The specification does not provide any evidence of the claimed variances recited in Table 3, such as the T to C substitution at position 732 of the CYP3A4 gene as being associated with any drug response, drug metabolism or is capable of modulating or altering the expression or activity of an encoded protein. Additionally, the specification does not provide any evidence that the claimed variance identified by the claimed isolated nucleic acid probe is associated with any disease or disease conditions. The specification only speculates that the claimed variance is indeed functional. Hence, the need for further research is clearly necessary to determine the function of the claimed variant as being associated with a drug response or a substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case, the claimed nucleic acid probe does

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not have an asserted or identified specific and substantial utility or the claimed variant being identified by the probe. In fact, it appears that the claim invention is only useful for identifying itself. The research contemplated by Applicant overall to characterize potential protein products, especially their biological activities does not constitute a specific and substantial utility. Identifying and studying the properties of a protein or gene itself, or the mechanisms in which the protein or gene is involved does not define a "real world" context of use. Similarly, the claimed use of identifying a protein or gene to detect variances with no asserted function is neither substantial nor specific due to being generic in nature and applicable to a myriad of nucleic acid molecules as noted by the plethora of nucleic acid molecules denoted in the Table 3. Further experimentation is deemed necessary to determine the functionality of the isolated nucleic acid probe and variant sequence as claimed. Note, because the claimed invention is not supported by a specific and substantial asserted utility or well established utility for the reasons set forth above, credibility has not been assessed.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 17-24 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 17-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 17-24 are indefinite at the recitation of "stringent conditions" because the hybridization conditions have not been defined in the specification or claims and it cannot be determined what hybridization conditions are considered as "stringent" in relations to the claimed inventions.

Conclusion

10. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CYNTHIA WILDER
PATENT EXAMINER
12/21/2005